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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,237	11/10/2000	Philip Henry Coelho	30195-pa	3030

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	7

DATE MAILED: 06/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/709,237	Applicant(s) COELHO ET AL.	
	Examiner Chih-Min Kam	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 and 10* is/are rejected.

7)☒ Claim(s) *11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, claims 9-11 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that all claims are closely related to the elected claims that they should all remain in the same application to preserve unity of the invention, and the product may be theoretically distinguishable from the method, however, the requirement under 35 U.S. C. 121 for the two inventions to be independent and distinct has not been met. This is not found persuasive because the inventions are distinct if the product can be made by another and materially different process (MPEP § 806.05(f)), in the instant case, the thrombin can be prepared by another method such as by adjusting the ionic strength of the blood and the pH of the plasma to cause precipitation of the thrombin component (page 4, lines 8-9 of the specification), thus, the process of Invention I is distinct from the product of Invention II. As such restriction is proper if two or more claimed inventions are either independent **or** distinct. See MPEP 803.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

2. Claim 11 is objected to because of the term "0.023μm", the concentration of $CaCl_2$ should be indicated as "0.023 μM".

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claim 9 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is drawn to autologous thrombin. As written, the claim does not explicitly indicate the hand of man. Insertion of "isolated" or "purified" in connection with autologous thrombin is suggested. See MPEP § 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is indefinite because of the use of the term "which provides fast clotting of less than five seconds which is stable for more than 15 minutes". The term "which provides fast clotting of less than five seconds which is stable for more than 15 minutes" renders the claim indefinite, it is not clear whether the thrombin or the clotting is stable for more than 15 minutes; it is also not clear under what condition the claimed thrombin provides fast clotting of less than five seconds and is stable for more than 15 minutes.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Regan *et al.* (U. S. Patent 5,674,482, filed August 9, 1991).

Regan *et al.* teach a concentrated fraction containing a polymeric compound in 50% aqueous ethanol was evaluated for anticoagulant activity using the APTT (activated partial thromboplastin time) assay at a concentration of 0.1 mg/ml (column 25, line 47- column 26, line 20). The APTT assay mixture contains normal pooled plasma, test compound solution, actin activated cephaloplastin reagent and $CaCl_2$ (column 22, lines 43-67). The assay mixture contains a fraction of a polymeric compound having ethanol, normal pooled plasma having prothrombin which is expected to convert to thrombin by addition of calcium chloride, which meets the criteria of claim 10.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reid *et al.* (U. S. Patent 5,476,771, December 19, 1995) taken with Gustafesson *et al.* (U. S. Patent 5,965,692, priority date Dec. 17, 1996).

Reid *et al.* teach a quantitative method for determining the plasma levels of a thrombi-specific inhibitor using quantitative thrombin time (QTT) assay, which contains human α-thrombin, VSC buffer containing calcium chloride (column 1, lines 28-33), and plasma sample containing inhibitor (column 4 lines 20-36, lines 55-59). However, Reid *et al.* do not disclose the use of ethanol in the assay mixture. Gustafesson *et al.* teach the amount of the active thrombin inhibitor that is excreted in urine after oral or parenteral administration was dissolved in ethanol:Solutol:water (5:5:90) and estimated by determining the thrombin time of the sample (column 12, lines 14-22). At the time of invention was made, it would have been obvious to one of ordinary skill in the art to use the quantitative thrombin time assay as taught by Reid *et al.* for estimating the amount of the active thrombin inhibitor in the sample as taught by Gustafesson *et al.* because QTT assay is relatively simple and provides superior results to standard conventional tests (e.g., APTT or standard thrombin time; abstract). Thus, the combined references result in

the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Conclusion

7. Claims 9 and 10 are rejected, and claim 11 is objected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

CHRISTOPHER S. F. LOW
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June 4, 2003